

## **Remarks**

### **I. Summary of the Office Action**

In the Office Action mailed September 10, 2010, the Office rejected claims 1, 2, 4-11, 13, and 17 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kotula (WO 97/42878). Claims 1 and 18 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Freudenthal (WO 01/49785). Claims 12 and 15 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kotula in view of Freudenthal and further in view of Solymar (US Pat. App. 2003/0149463), and claims 16 and 19-23 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kotula in view of Chanduszko (U.S. Pat. App. 2005/0043759)

Claims 1-2, 4-13, and 15-23 are currently pending in the application. Of these claims, claims 1 and 19 are in independent format, and the rest are in dependent format. Applicants submit that the claims, as amended, distinguish over the cited art.

### **II. Status of the Claims**

Applicants have amended independent claims 1 and 19 to more particularly point out and distinctly claim the subject matter that Applicant regards as the invention, and thus to better define the inventive advance over the cited art.

Specifically, claims 1 and 19 now recite that first and second occluding bodies are “formed as thin disk-shaped elements separate from said elongate members.” These amendments find support in the specification on page 6, lines 28-33, page 7, lines 16-18, and Figures 1-4. Note that these disk-shaped elements are unfurled like an umbrella and are “fluid tight”, as stated on page 6, lines 31-33 and page 8, lines 14-15 of the specification.

Further, claims 1 and 19 now recite that the third portions (intermediate portions for claim 19) of each elongate member collapse upon themselves in a spiral manner upon formation

of said fixation structures to bring said occluding members into close facial proximity, the fixation structures each extending radially beyond a perimeter of the adjacent occluding body. These amendments find support throughout the specification, for example, on page 6, lines 13-16, page 7, lines 16-18, 20-33, page 8, lines 1-10, and Figures 1-4.

Accordingly, no new matter has been added by these amendments.

### **III. Response to Rejections**

Applicant submits that all of the pending claims are in condition for allowance in view of the amendments made to independent claims 1 and 19. At a minimum, none of the cited references show third portions (or intermediate portions for claim 19) of each elongate member that collapse upon themselves in a spiral manner upon formation of said fixation structures to bring said occluding members into close facial proximity, the fixation structures each extending radially beyond a perimeter of the adjacent occluding body. This constitutes new and novel structure that allows a good seal to be formed on opposing sides of an aperture in a body passage or heart, for example.

Claim 19 furthermore sets forth that the elongate members are separate from one another, in that they are capable of independent movement relative to one another. This is in direct contrast to Kotula. At best, Kotula discloses an occluder consisting of a metal braided fabric that is “generally tubular.” *Kotula*, pp. 6, lines 6-9; p. 7, line 30 to p. 8, line 1; Figures 1A and 1B. This fabric is placed in a mold and heat treated to substantially set a desired shape (i.e. providing shape memory), so that it will tend to assume the preferred configuration of the mold unless constrained from doing so. *Id.* at p. 7, lines 3-18. Accordingly, “[i]n instances where the device is improperly deployed on a first try, the device 300 may be recovered by pulling the delivery device 312 proximally, thereby retracting the device 300 back into the delivery catheter

314 prior to a second attempt at positioning the device 300 relative to the defect.” *Id.* at p. 29, line 30 to p. 30, line 2.

Kotula’s tubular braided fabric is a criss-crossing mesh. Comparing Kotula’s Figures 1A and 1B with Applicant’s Figure 1, as shown below, it is clear that Kotula does not teach or disclose “elongate members separate from one another and capable of independent movement relative to each other between said ends,” as recited in claim 19.

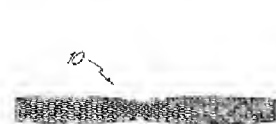


Fig. 1A

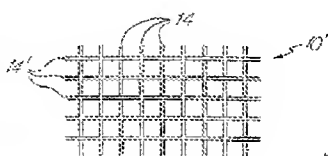
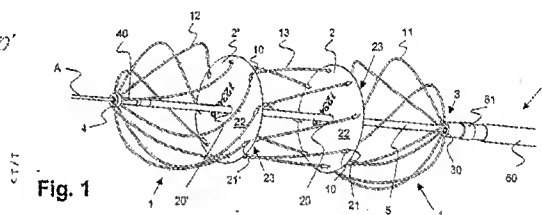


Fig. 1B

Kotula Figs 1A-B



Applicant's Fig. 1

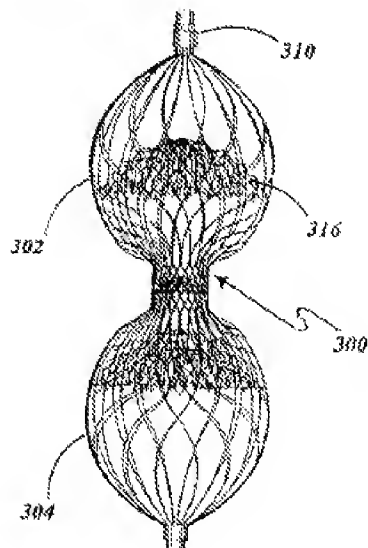
Note also that the elongate members form first and second fixation structures with loops that extend beyond the perimeter of the respective occluding member. This yields an increased cross-section for the same, which again is in direct contrast to Kotula’s free floating fibers.

Moreover, in the relaxed unstretched state, Kotula’s occluder has two disks 302, 304 aligned in spaced relation and linked together by a short cylinder 306. *Kotula*, p. 27, lines 15-17. And Kotula’s occluder operates through the formation of thrombi in and on the device that eventually results in an occluding body. *Id.* at p. 20, lines 29-30. “The device can contain polyester fibers 316 (see Figures 15 and 18)” disposed within the space of the disks 302, 304 but not attached to the strands of the metal fabric. *Id.* at p. 29, lines 24-27. These polyester fibers 316 act as a thrombogenic agent that speeds up the thrombosis but the polyester fiber 316 does not act as an occluding body on its own. *Id.* at p. 20, line 30 to p. 21, line 2.

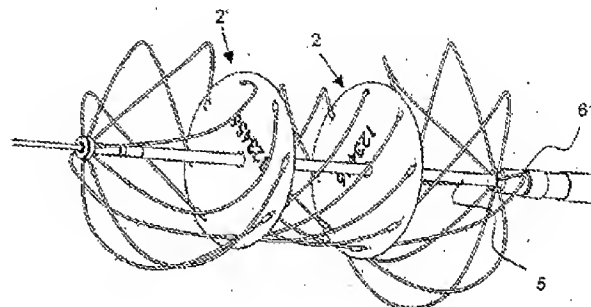
Note the obvious contrast between Kotula’s free-floating polyester fibers 316, shown in

Figure 18 below, and an embodiment of Applicant's claimed first and second occluding bodies 2, 2' that are attached to the elongate members, shown in Figure 3 below.

**Fig.18**



Kotula's Fig. 18



**Fig. 3**

Applicant's Figure 3

Kotula's free-floating polyester fibers 316 cannot be considered an occluding body that closes an internal passage. And Kotula's disclosure underscores this point by specifically stating that "thrombi will occlude the [device]," not the fibers themselves. *Id.* at p. 20, line 30 (emphasis added). As such, Kotula does not disclose either "a first occluding body being attached to the elongate members" or "one second occluding body being attached to the elongate members," as recited in independent claim 1.

Nor do Kotula, Freudenthal and Chandusko have the thin disk-like elements for occluding bodies. As discussed above, Kotula deploys free floating fibers that must accumulate thrombi over time to provide a preclusive effect. Freudenthal likewise employs a "netting-like structure" and notes that it "is not required that the membrane 8 provide for a hermetically sealing when implanted in the defect opening, but the provision of a suitable resistance against flow through the implant will do." *Freudenthal*, page 14, line 30 to page 15, line 2. And

Chandusko's occluder simply consists of tube 22 and loops 32 and 42, which are open and do not employ a membrane of any kind. *Chandusko*, Figures 2A-D, 4A-B, ¶ [0062].

#### **IV. Conclusion**

In view of the foregoing, Applicant submits that all of the pending claims are in condition for allowance. Therefore, Applicant respectfully requests favorable reconsideration and allowance of all the claims (1-2, 4-13, and 15-23). If the Examiner would like to discuss any aspect of this case, the Examiner is invited to telephone the undersigned at 312-913-0001.

Respectfully submitted,

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Date: May 10, 2011

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